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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/701,698

11/05/2003

Ricardo Blank

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01/25/2008

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

EXAMINER

BOGART, MICHAEL G

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

01/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/701,698

Applicant(s)

BLANK ET AL.

Examiner

Michael G. Bogart

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,7,8 and 10-29 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,7,8,10-24 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

1. Claims 2, 3, 7, 8, 13, 17-24 and 27-29 are rejected under 35 U.S.C. § 103 as being unpatentable over Kawaguchi *et al.* (CA 2 432 623 A1 or US 2004/0104246 A1; hereinafter “Kawaguchi”; all page numbers, reference numbers and figures below refer to the Canadian patent) in view of Knierbein (US 6,485,479 B1).

Regarding claims 2 and 20, Kawaguchi teaches a connector device (12) capable of connecting a feeding line (30) of an enteral administration set (30, 31) to a laminated paper packaging system (20) containing a composition, the connector device comprising:

a rigid tube part (112) capable of being sealingly attached to the feeding line (30) of the enteral administration set, the tube part (112) defining a first part of the a passageway (112g, 112c) allowing the flow of the composition contained in the laminated paper packaging system (20) to the feeding line (30) of the enteral administration set (30, 31), and

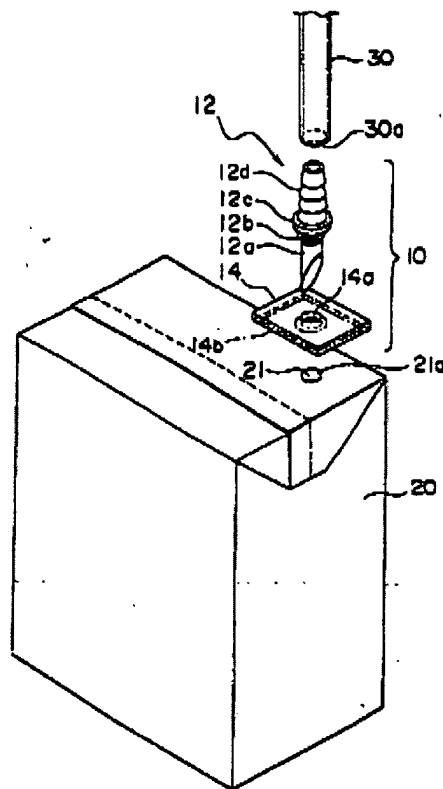
first means (112b, 112s) capable of threadably attaching the rigid tube part (112) to the laminated paper packaging system (20), whereby the connector (12) is screwed to the laminated paper packaging system (20), the first means (112b, 112s) further defining a second part of the passageway (112g, 112b) when threadably attached to the laminated paper packaging system (20), and

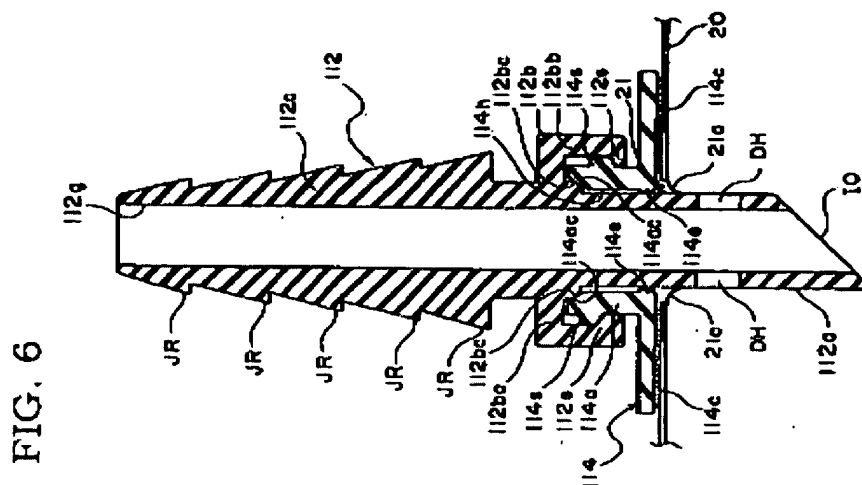
second means (112a) for opening the laminated paper packaging system upon connecting the connector device (12) onto the laminated paper packaging system (20).

Kawaguchi does not teach a cutting member rotatable with the connector device upon screwing the connector device onto the frame-like member of the packaging system, the cutting

member projecting toward the surface such that the cutting member is capable of first cutting the surface only after engagement of the second threaded portion of the connector device with the first threaded portion of the packaging system (see figures 1 & 6, infra).

FIG. 1





Knierbein teaches a cutting member (21) rotatable with the connector device (20) upon screwing the connector device (20) onto the frame-like member (4), the cutting member (21) projecting toward the surface such that the cutting member (21) is capable of first cutting a sealed (18) surface only after engagement of a second threaded portion of the connector device (20) with a first threaded portion (see fig. 4, *infra*). This offers the advantage that the connector can be pre-engaged to a container in a sterile manner and hooked up to a patient without rupturing the container. When it is time to start treatment, feeding, etc., a caregiver just needs to rotate the connector.

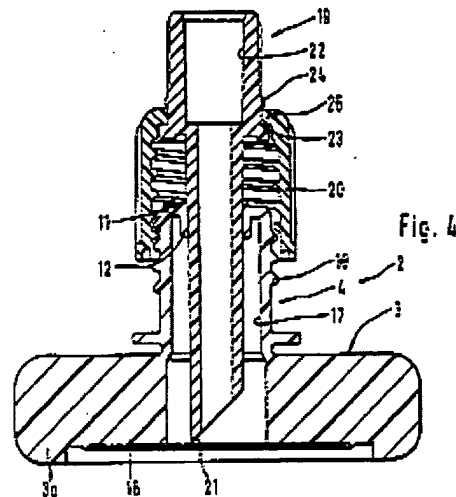
At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the functional features of Knierbein's sterile connector to the laminated paper packaging system of Kawaguchi in order to provide a sterile means of hooking up a patient to the system prior to starting treatment.

Furthermore, where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known

technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

The claims include functional limitations such as "for connecting a feeding line of an enteral administration set to a laminated paper packaging system," "first means" and "second means." While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the

preamble, or elsewhere in a claim, then it meets the claim. The combination of Kawaguchi and Knierbein can perform this function.



Regarding claim 7, Kawaguchi teaches tubular first spike (112a) capable of penetrating a first surface (20, 21) of the laminated paper packaging system (20) and defining a second part of the passageway (112g, 112a)(see fig. 6, supra).

Regarding claim 13, Kawaguchi teaches a prefabricated enteral administration system comprising an enteral administration set (30) and a connector device (12) non-releasably connected to the enteral administration set (30).

Regarding claims 17 and 18, Kawaguchi teaches a kit comprising prefabricated enteral administration system (30) according and a laminated paper packaging system (20) containing a composition capable of being enterally administered to a patient.

Regarding claim 19, the Kawaguchi's connector (12) requires significant force to remove from the enteral administration set (30) is interpreted herein as being relatively non-releasable compared to a connector that lacks barbs (JR)(fig. 6).

Regarding claim 21, Knierbein teaches a cutting member (21) that is integral with the first means (20).

Regarding claim 22, Knierbein teaches a connector (20) that is non-releasably connected to a container (see col. 4, lines 30-35).

Regarding claim 23, Kawaguchi teaches a kit comprising prefabricated enteral administration system (30) according and a laminated paper packaging system (20) containing a composition capable of being enterally administered to a patient.

Regarding claims 24 and 29, Kawaguchi teaches that the laminated paper packaging system (20) includes a first surface with a frame-like member (114) defining an annular threaded projection (114s), and wherein the first means (112b, 112s) comprises a threaded annular portion (112s) complementary to the threaded projection (114s) of the laminated paper packaging system (20).

Regarding claim 3, Kawaguchi teaches that the second means (112a) comprises a cutting member (12a, 112a) protruding downwards from the connector device (12, 112) towards the laminated paper packaging system (20) for cutting the laminated paper packaging system (20) when the connector (12, 112) is attached onto the frame-like member (114)(abstract). Knierbein teaches a cutting member (21) rotatable with the connector device (20) upon screwing the connector device (20) onto the frame-like member (4), the cutting member (21) projecting toward the surface such that the cutting member (21) is capable of first cutting a sealed (18) surface only after engagement of a second threaded portion of the connector device (20) with a first threaded portion (see fig. 4, *infra*).

Regarding claims 27 and 28, Kawaguchi teaches that the attachment means (14) for fixedly attaching the connector device (12) to the laminated paper packaging system (20) comprises an annular rim (14) having a surface facing towards the first surface of the laminated paper packaging system (20), an adhesive layer (14b) being provided on the first surface for attaching the connector (12) to the laminated paper packaging system (20) upon penetration of the spike (12a).

Regarding claim 8, Kawaguchi teaches that the attachment means for fixedly attaching the connector device (12) to the laminated paper packaging system (20) comprises two rims (112b, 112s) extending in parallel around the spike (14a) axially spaced from each other at a predetermined distance, that rim (112b) located nearer to the point of the spike (12a) being made from a flexible material while that rim (112c) located farther from the point of the spike (14a) being made from a rigid material.

2. Claims 14 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi and Knierbein as applied to claims 2, 3, 7, 8, 13, 17-24 and 29 above, and further in view of Quinn *et al.* (US 4,895,275) and Schafer (US 5,993,422 A).

Kawaguchi and Knierbein do not teach a pump unit or means of controlling administration of fluid to a user of that device.

Quinn teaches the use of a TETRA BRIK type container as an enteral feeding device.

Schafer teaches a device for dosing medical fluids which includes a pump (2)(abstract).

At the time of the invention, it would have been obvious to modify the fluid container of Kawaguchi and Knierbein so that it functions as a enteral device as taught by Quinn, and to

further add the dosing means and pump of Schafer in order to provide automation of the complete system.

Furthermore, where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). See *Ex Parte Smith*, supra.

3. Claims 15 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi and Knierbein as applied to claims 2, 3, 7, 8, 13, 17-24 and 29 above, and further in view of Quinn and Hindricks (US 3,001,525).

Kawaguchi and Knierbein do not teach an intermediate bag.

Quinn teaches the use of a TETRA BRIK type container as an enteral feeding device.

Hendricks teaches parenteral equipment that includes an intermediate bag (1) for mixing solutions.

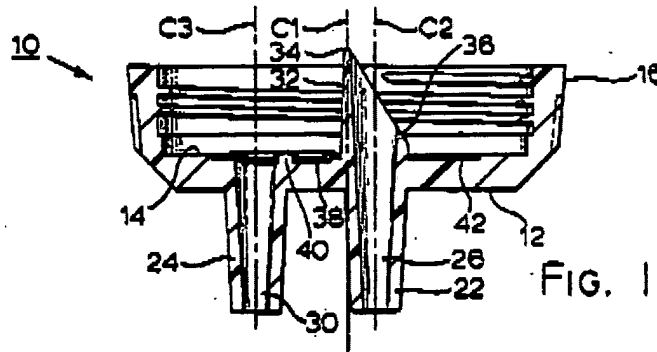
At the time of the invention, it would have been obvious to modify the fluid container of Kawaguchi and Knierbein so that it functions as a enteral device as taught by Quinn, and to further add the intermediate bag of Hendricks in order to provide a means of reconstituting solutions.

Furthermore, where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, supra.

4. Claims 10-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi and Knierbein as applied to claims 2, 3, 7, 8, 13, 17-24 and 29 above, and further in view of Dickerhoff *et al.* (US 4,997,429).

Kawaguchi and Knierbein do not teach a vent or valve.

Dickerhoff teaches an enteral bottle cap (10) with a vent valve (24, 38) that permits entry of filtered air into the container while prevention liquid from exiting the container (see figure 1, *infra*). This provides for unimpeded flow of liquid through outlet (26).



At the time of the invention, it would have been obvious for one of ordinary skill in the art to add the vent valve of Dickerhoff to the connector of Kawaguchi and Knierbein in order to provide a means of venting the container while hooked up to a patient line.

Furthermore, where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, supra.

Regarding claim 12, mere duplication of parts is not sufficient to patentably distinguish the invention over the prior art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Response to Arguments

Applicant's arguments regarding claims 2, 3, 7, 8, 10-24 and 27-29, filed 31 October 2007 have been fully considered but they are not persuasive.

In response to applicant's argument that Knierbein's coupler has a boat-shaped bottom portion that is structurally divergent and incompatible with the bottom portion of the coupler of Kawaguchi, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

Here, Knierbein is being applied only for the concept that the threaded coupling allows the coupler to be pre-engaged prior to the spike piecing the container.

Regarding applicant's argument that there is no motivation or suggestion to combine Kawaguchi and Knierbein, where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, supra. There is no requirement for a motivation or suggestion to combine the references.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.


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In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Bogart
21 January 2008

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

